

**REMARKS**

In the Office Action, claims 23 and 27-29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Claims 23 and 27-29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Claim 1 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claims 1-23 and 27-29 are provisionally rejected on the ground of non-statutory double patenting over claims 1-23 of co-pending Application No. 10/962,960 (hereafter “the ‘960 application”).

Claims 1-23 and 27-29 are provisionally rejected on the ground of non-statutory double patenting over claims 1-37 of copending Application No. 10/573,516 (hereafter “the ‘516 application”).

Claims 23 and 27 to 29 are herein cancelled without prejudice.

Claims 1-22 are herein amended.

No new matter has been introduced by the amendments.

Claims 1-22 are pending in the case.

Reconsideration of the present application in view of the foregoing amendments and the remarks below is respectfully requested.

**Claim Rejections under 35 U.S.C. § 112**

(1) Claims 23 and 27-29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

(2) Claims 23 and 27-29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

Claims 23 and 27-29 are herein cancelled without prejudice solely to accelerate the prosecution of the case. Accordingly, the rejections of these claims are now moot. Applicants expressly reserve the right to pursue the subject matter of the cancelled claims in a continuation application.

(3) Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Specifically, the Office Action states that “[w]ritten description is missing for ‘exocyclic double bond’ as it pertains to X and Z” and “the instant specification does not provide written description for solvent complexes and morphological forms.”

Claim 1 is herein amended to delete the passage, “or X and Z represent together with the carbon atom to which they are attached an exocyclic double bond which bears an aryl substituent”. Further, the passage “solvent complexes, and morphological forms” is herein deleted.

Accordingly, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, be withdrawn.

Claim 1 is further amended for editorial purposes in compliance with the U.S. practice as well as to recite Markush groups in an alternative form.

(4) Claim 1 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Specifically, the Office Action states that “claim 1 is ambiguous due to the use of ‘exocyclic double bond which bears an aryl substituent.’”

As described above, the relevant portion of claim 1 is herein deleted and, therefore, the rejection of claim 1 under 35 U.S.C. § 112, second paragraph, as being indefinite should be withdrawn.

#### **Claim Rejections under Double Patenting**

(1) Claims 1-23 and 27-29 are provisionally rejected on the ground of non-statutory double patenting over claims 1-23 of the co-pending '960 application.

Claims 23 and 27-29 are herein cancelled without prejudice and, therefore, the rejections of these claims are now moot.

Specifically, the Office Action states that “the claims of the copending application fall within the instant scope” and that “there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application.”

Applicants respectfully traverse the rejection.

Claim 1 of the '960 application is directed to “[t]he compound, 1-[2-(4-Benzyl-4-hydroxy-piperidin-1-yl)-ethyl]-3-(2-methyl-quinolin-4-yl)-urea [...] ***in the form of a crystalline salt or a non-defined crystalline salt hydrate.***” (emphasis added). Such claim would have no basis in the present application because the present application is not enabling with regard to preparing said compound in the form of a crystalline salt or non-defined salt hydrate.

Accordingly, claim 1 of the present application has been amended for clarification and the recitation of "solvent complexes, and morphological forms" has been deleted. Applicants, therefore, believe that the claims of the copending '960 application do not fall within the scope of the instant application.

Accordingly, Applicants respectfully request that the provisional rejection of claims 1-22 on the ground of non-statutory double patenting over claims 1-23 of the copending '960 application, be withdrawn.

(2) Claims 1-23 and 27-29 are provisionally rejected on the ground of non-statutory double patenting over claims 1-37 of the copending '516 application.

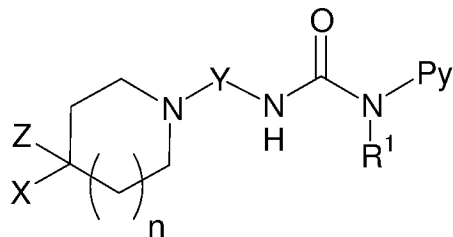
Claims 23 and 27-29 are herein cancelled without prejudice and, therefore, the rejections of these claims are now moot.

Specifically, the Office Action states that "[t]he claims of the copending application fall within the instant scope."

Applicants respectfully traverse the rejection.

The scope of the instant application and that of the '516 application differ in the respective definitions of the group Py as used in the respective general formulae.

Claim 1 of the instant application is directed to a compound of General Formula 1,

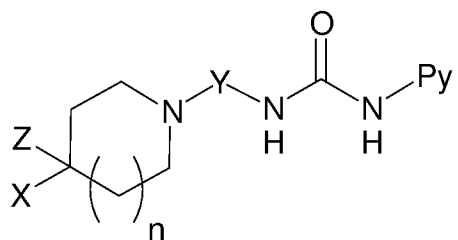


## General Formula 1

wherein:

“Py represents pyridin-4-yl mono-substituted in position 2 with  $-NR^2R^3$ ; pyridin-4-yl disubstituted in position 2 with  $-NR^2R^3$  and in position 6 with lower alkyl or arylalkyl; unsubstituted quinolin-4-yl; quinolin-4-yl mono-substituted in position 2 with lower alkyl; quinolin-4-yl di-substituted in position 2 with lower alkyl and in position 6, 7, or 8 with halogen, lower alkyl, or arylalkyl; 2-hydroxymethyl-quinolin-4-yl; 7-methyl-[1,8]naphthyridin-4-yl; 5,6,7,8-tetrahydro-[1,8]naphthyridin-4-yl; 8-benzyl-5,6,7,8-tetrahydro-[1,8]naphthyridin-4-yl; 8-methyl-5,6,7,8-tetrahydro-[1,8]naphthyridin-4-yl; 2,3-dihydro-1H-pyrrolo[2,3-b]pyridin-4-yl; 1-methyl-2,3-dihydro-1H-pyrrolo[2,3-b]pyridin-4-yl; or 1-benzyl-2,3-dihydro-1H-pyrrolo[2,3-b]pyridin-4-yl; . . . .”

In contrast, claim 1 of the '516 application is directed to compounds of



## General Formula 1

wherein:

“Py represents pyridin-4-yl which is disubstituted in positions 2 and 6, whereby the substituent in position 2 is  $C_{1-7}$ -alkyl, aryl- $C_{1-7}$ -alkyl, or (*E*)-2-aryl-ethen-1-yl, and the substituent in position 6 is hydrogen or  $C_{1-7}$ -alkyl; . . . .”

Specifically, the compounds of claim 1 of the instant application differ from the compounds of the '516 application in view of one of the substituents of the disubstituted pyridin-4-yl ring which is:

- a group  $-NR^2R^3$  in the definition of Py in claim 1 of the instant application; instead of
- hydrogen or  $C_{1-7}$ -alkyl in the definition of Py in claim 1 of the '516 application;

and the second substituent being lower alkyl or arylalkyl in the instant application, while  $C_{1-7}$ -alkyl, aryl- $C_{1-7}$ -alkyl, or (*E*)-2-aryl-ethen-1-yl in the '516 application. It should be noted that positions 2 and 6 of a pyridin-4-yl group are equivalent. Thus, Applicants believe that the claims of the co-pending '516 application do not fall within the scope of the instant claims.

Accordingly, Applicants respectfully request that the provisional rejection of claims 1-22 on the ground of non-statutory double patenting over claims 1-37 of the copending '516 application, be withdrawn.

#### **Additional Claim Amendments**

Claim 22 is herein amended to delete five compounds that do not fall within the scope of claim 1 as amended.

Claims 2-22 are herein amended to include a pharmaceutically acceptable salt of each of the recited compounds. Support for the amendment can be found, for example, page 6, lines 22-29, of the present specification.

No new matter has been introduced by the amendments.

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance.

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Respectfully submitted,

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